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From: Smith, Bonnie
Sent: Tue 2/4/2014 4:19:04 PM
Subject: W Va. Gazette: Chemical limit in water reflects caution, limited data, CDC says -- FYI.... reporting from 1/16/14

A story from early on.... Charleston Gazette... I'm sure you are aware of this. -bonnie

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Chemical limit in water reflects caution, limited data, CDC says

By Ken Ward Jr.

By David Gutman

The U.S. Centers for Disease Control today defended its 1-part-per-million threshold for acceptable levels of Crude MCHM, saying it was made using cautious, conservative estimates.

But agency officials also conceded that it's "almost as if we're learning as we go" in dealing with a chemical spill that fouled the drinking water supply that serves nearly a third of a million West Virginians.

Late Wednesday evening, the state Department of Health and Human Resources, acting on the CDC's advice, recommended that pregnant women should not drink tap water until there is no Crude MCHM, the coal-processing chemical that spilled into the Elk River last week, detectable in the water.

And then this morning -- after refusing repeated interview requests since Friday -- the CDC made Dr. Vikas Kapil, chief medical officer for the agency's National Center for Environmental Health, available for an interview with The Charleston Gazette.

Kapil stressed that new recommendation to the state was made out of an "abundance of caution" and said that pregnant women who have been drinking the water since "do not use" orders began to be lifted on Monday should not expect adverse effects.

"We would not expect that at the levels we're talking about that we would expect any adverse health effects, either for the mom or their baby or their unborn babies," Kapil said.

There are no regulatory standards for MCHM, also known as 4-methylcyclohexanemethanol, under either federal or state rules, and prior to the spill last week there appears to have been little attention given to setting workplace, environmental or public health exposure guidance.

But since Friday, Gov. Earl Ray Tomblin and other state officials have been citing the CDC's 1 ppm figure, and West Virginia American Water Company has been advising residents that they could resume using tap water when tests showed levels of MCHM below that level.

In today's interview, Kapil said that the new advisory was not made because of newly discovered information.

"It's really just out of an abundance of caution, exposure during pregnancy and reproductive toxicology is a challenge," Kapil said. "We often don't have a lot of reproductive toxicology information available on those exposures."

But in Wednesday letter to DHHR Secretary Karen Bowling, CDC Director Dr. Thomas Frieden specifically noted that "since making the initial calculation, scientists have obtained additional animal studies about MCHM. These are currently being reviewed.

"At this time, the scientists continue to recommend 1 ppm as a protective level to prevent adverse health effects," Frieden wrote. "However, due to limited availability of data, and out of an abundance of caution, you may wish to consider alternative drinking water source for pregnant women until the chemical is at non-detectable levels in the water distribution system."

Richard Denison, a biochemist with the Environmental Defense Fund, has been following the West Virginia situation and writing about the CDC's risk assessment efforts on his organization's blog.

Writing late Wednesday, Denison noted that the CDC letter made it appear that the newly-obtained studies played some role in the federal agency's recommendation and the state's action. That, Denison said, "raises the question as to whether the new animal studies suggest a potential for developmental toxicity or a related effect.

"Clearly something prompted the issuance of the advisory," Denison wrote. "This new development, I believe, lends even greater weight to the need for immediate public release of available studies and the methodology."

On Thursday afternoon, Sen. Joe Manchin, D-W.Va., and Rep. Shelley Moore Capito, R-W.Va., wrote to Frieden requesting the detailed methodology behind their calculations, the information that led them to change the advisory for pregnant women, the date when CDC became concerned about lower level exposure in pregnant women and the CDC's level of confidence in the 1 part per million standard going forward.

"It is particularly concerning that as many as 150,000 people who had been under a 'do-not-use' water order were told that their water supply was safe for use before the CDC's recommendation that pregnant women should consider an alternate drinking water source," they wrote. "We are deeply disappointed in the CDC for recommending a screening level before receiving all relevant studies and information, which has resulted in confusion, fear and mistrust among Kanawha Valley residents."

Kapil said that the advisory for pregnant women only applied to drinking water and that tap water below 1 part per million should still be considered safe for washing, bathing and other uses.

He also said that the advisory did not apply to women who are breastfeeding, infants or other associated populations.

The CDC's 1 part per million standard comes from two private studies from the 1990s that were done on animals.

Kapil could not say if government officials would publicly release those studies, but he said the CDC was working with the National Library of Medicine and other federal agencies to summarize a report of their work.

Celeste Monforton, a public health researcher a Georgetown University, said that federal and state officials need to release all of the information they used to come up with the 1 part per million standard.

"If the agencies have confidence in telling the public that a 1 ppm exposure limit is safe, the public has a right to know the data, studies and methodology for deriving that level," Monforton said. "That right means nothing if those with the information won't tell you when they will get it."

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The existence of one of those studies was previously disclosed on a "material safety data sheet" issued by Eastman Chemical Co., whose plant in Kingsport, Tenn., manufactured the MCHM. That study established what's called an "LD50," a level at which half of the rats exposed to the material died.

Eastman officials, responding to email questions, have refused to provide copies of any of their studies or data about the potential impacts of MCHM.

"Eastman's toxicological studies for crude MCHM are not published in scientific journals and therefore are not what are commonly referred to as peer-reviewed studies," said Maranda Demuth, an Eastman spokeswoman. "The studies, however, were conducted under Good Laboratory Practices, and according to OECD guidelines, at a reputable laboratory where rigorous internal review processes were performed.

In the interview, Kapil disclosed the existence of another study used by the CDC. He said that it resulted in a figure called the No Observable Adverse Effects Level (NOAEL). That figure shows the maximum amount of chemical in which there are no biological or health effects visible in the test animals, which Kapil thought were either rats or guinea pigs.

The NOAEL for Crude MCHM was 100 milligrams per kilogram of body weight, Kapil said.

To that number, toxicologists at the CDC applied three safety factors, to try to account for uncertainty.

The first safety factor accounts for the variation between animals and humans.

The second safety factor accounts for variation within humans, as some populations -- the elderly, children, those with pre-existing conditions -- could be more vulnerable.

The third safety factor accounts for how little information is available on Crude MCHM.

Each safety factor was given a weight of 10. They were multiplied by each other to produce a total safety factor of 1,000.

The NOAEL was then divided by 1,000, giving a result of 0.1 milligrams per kilogram, which works out to 1 part per million in water.

Kapil said that at every step, they used the most conservative estimates.

"Some people apply smaller factors, sometimes three, sometimes four, depending on what it is you're talking about, but we applied the highest so we feel pretty comfortable that the one part per million number is a number that would not be associated with any adverse effects for humans, based on this methodology," he said.

Asked if he would drink the water in Charleston if it was at a level of 0.9 parts per million, Kapil responded, "Absolutely. I would have no hesitation whatsoever."

But both Kapil and Tom Skinner, a CDC press officer, stressed that they did not have as much information as they would like.

"Ideally we would like to have a whole host of studies like human epidemiology studies, human toxicology studies, all of that information available to us," Kapil said. "We do have limited animal data and from that animal data we have to somehow figure out a way to extrapolate for decision-making related to these types of human exposure."

Skinner said that the CDC did not have much experience dealing with a fast-moving situation of this magnitude.

"This whole situation is very fluid, so it's almost as if we're learning as we go," he said. "This experience that we're involved with now is actually going to provide us with a lot of information to base future decisions on."

In a Facebook posting after the DHHR's advisory to pregnant women, West Virginia American Water commented that the company "does not set water quality standards."

"Our responsibility is to follow the rules and guidelines established by federal and state

regulatory agencies, such as the CDC, EPA, West Virginia Department of Health and Human Resources' Bureau for Public Health and the West Virginia Department of Environmental Protection," the company said. "West Virginia American Water has followed the regulatory guidelines and testing protocols required to lift the Do Not Use order ban, and we are fully confident that we are providing customers with drinking water that meets all regulatory standards."

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